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510(k) SUMMARY

JUN 11 2008

Submitted by:

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Date Prepared: February 7, 2008

Trade Name: Cure Catheter™ Closed System

Common Name: Urological Catheter

Classification Name: Catheter, Urological

Device Class: II

Procode: KOD/FCM

CFR Reference: 876.5130

Predicate Device: Rusch MMG/O'Neil Catheter (K010420)

Predicate 510(k) #: K010420 (Rusch)

Device Description: The Cure Catheter™ Closed System is an intermittent urinary catheter attached to a collection bag and intended to be used by males and females for the purpose of bladder drainage. It is manufactured with conventional medical grade, latex-free, biocompatible materials. The tip has been designed to eliminate trauma to the urethra and is provided in a variety of sizes in sterile, single-use packages. The Cure Catheter™ Closed System is also offered as part of a complete kit.

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Intended Use:	The Cure Catheter™ Closed System is an intermittent urinary catheter attached to a collection bag that is inserted through the urethra and indicated for the purpose of bladder drainage for males and females. The urinary catheter comes in a variety of sizes packaged sterile for single-use.
Technology Comparison:	The Cure Catheter™ Closed System is substantially equivalent to the predicate device. The devices are similar in function, composition, and intended use.
Nonclinical Testing:	Standard biocompatibility tests were performed on the Cure Catheter™ Closed System to establish device safety. The tests and assays performed are typically performed for these medical devices. All tests were performed in accordance with US FDA General Program Memorandum #G95-1 and Part-10993-1 of the International Standard Organization (ISO) Standard (Biological Evaluation of Medical Devices) by North America Science Associates, Inc. (NAmSA). The Cure Catheter™ Closed System met the acceptance criteria for all tests conducted and is considered biocompatible under the conditions tested.
Conclusion of Comparison:	The Cure Catheter™ Closed System is substantially equivalent to the currently-marketed predicate device, the Rusch MMG/O'Neil Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2008

Cure Medical, LLC
c/o James Smith, Ph.D., RAC
Consultant, Regulatory Affairs
DeFerris, Inc.
29442 Pointe Royale
LAGUNA NIGUEL CA 92677

Re: K080881
Trade/Device Name: Cure Catheter™ Closed System
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Codes: KOD and FCM
Dated: May 22, 2008
Received: May 27, 2008

Dear Dr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K080881

INDICATIONS FOR USE

510(k) Number (if known): K080881

Device Name: Cure Catheter™ Closed System

Indications for Use:

The Cure Catheter™ Closed System is an intermittent urinary catheter attached to a collection bag that is inserted through the urethra and indicated for the purpose of bladder drainage for males and females. The urinary catheter comes in a variety of sizes packaged sterile for single-use.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K080881

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